



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0067; FRL-10017-52]

Streptomycin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of streptomycin in or on the fruit, citrus, group 10-10 and fruit, citrus, group 10-10, dried pulp. Geo Logic Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0067, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information

on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-

HQ-OPP-2016-0067 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0067, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of April 25, 2016 (81 FR 24044) (FRL-9944-86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8427) by Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33409. The petition requested that 40 CFR 180.245 be amended by establishing tolerances for residues of streptomycin in or on citrus fruit, crop group 10–10 at 0.5 ppm and citrus, dried pulp at 3.5

ppm and by removing the existing tolerances for grapefruit.

In addition, in the *Federal Register* of September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8236) by Interregional Research Project No. 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested the establishment of tolerances for residues of streptomycin in or on grapefruit at 0.15 ppm, grapefruit, dried pulp at 0.63 ppm, and fruit, pome, group 11-10 at 0.25, as well as several amendments to the existing tolerances in 40 CFR 180.245 as follows: (1) moving the existing tolerances for streptomycin on celery, pepper, and tomato from paragraph (a)(2), and potato from paragraph (a)(3) to the table in paragraph (a)(1); (2) modifying the existing tolerance for tomato from 0.25 ppm to 0.5 ppm; (3) removing the existing time-limited tolerances for grapefruit and grapefruit, dried pulp in paragraph (b) upon establishment of the permanent tolerances for grapefruit and grapefruit, dried pulp; (4) removing the existing tolerance for fruit, pome, group 11 upon establishment of the tolerance for fruit, pome, group 11-10; and (5) modifying the tolerance expression and creating a single paragraph and table under §180.245(a) to provide that in general tolerances are established for residues of the fungicide streptomycin, including its metabolites and degradates, in or on the commodities in the table to the paragraph. Compliance with the tolerance levels specified in the table is to be determined by measuring only streptomycin (O-2-Deoxy-2-(methylamino)-α-L-glucopyranosyl-(1-2)-O-5-deoxy-3-Cformyl-α-L-lyxofuranosyl-(1-4)-N,N'-bis(aminoiminomethyl)-D-streptamine) in or on the commodity.

The documents referenced summaries of the petitions prepared by the petitioners, which are available at <http://www.regulations.gov>. in the following dockets: EPA-HQ-OPP-2016-0067 for PP 5F8427 and EPA-HQ-OPP-2014-0134 for PP 4E8236. No comments were received in response to the notice of filing for PP 5F8427; eighteen comments were submitted in response to the notice of filing for PP 4E8236 although none were relevant to the streptomycin tolerance.

Based upon review of the data supporting the petitions, EPA is establishing the tolerances

at different levels than requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for streptomycin including exposure resulting from the tolerances modified by this action. EPA's assessment of exposures and risks associated with streptomycin follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings and republishing the same sections is unnecessary; EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for streptomycin, in which EPA

concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to streptomycin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological Profile. There are no guideline toxicity studies available to assess pesticidal uses of streptomycin. The toxicity of streptomycin was assessed using the extensive published literature on drug use of streptomycin in humans and in animals, as well as with several toxicity summaries provided by the FDA. Injections of streptomycin as a drug (up to a gram), at doses much higher than expected from dietary or residential routes of exposure to pesticidal uses, can cause inner ear toxicity resulting in vestibular problems with loss of balance or equilibrium. Injections also sometimes cause hearing loss and mild, reversible kidney toxicity. Children born to mothers treated with streptomycin injections have sometimes had hearing loss. No teratogenic effects were noted in a non-guideline rabbit developmental study. In a non-guideline 2-year rat feeding study, the only adverse effect noted was reduced body weight in males; an increase in treatment-related tumors was not reported. The acute oral toxicity for streptomycin is very low; the LD₅₀ was 9,000 mg/kg in both rats and mice.

Toxicological Points of Departure/Levels of Concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment, see Unit IV.A. of the March 15, 2017 rulemaking (82 FR 13759) (FRL-9957-65).

Exposure Assessment. EPA's dietary exposure assessments for the permanent tolerances on the citrus fruit crop group 10-10 and dried citrus pulp relied on tolerance-level residues for all crops and an assumption of 100 percent crop treated (PCT). EPA's aggregate exposure assessment incorporated this assumed dietary exposure, as well as exposure in drinking water and from residential sources, which have not changed since the last assessment. The assessment also considered aggregate risk as a result of the pharmaceutical uses of streptomycin. For a description of the rest of the EPA approach to and assumptions for the exposure assessment, see

Unit IV.B. of the March 15, 2017 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit IV.C. of the March 15, 2017 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate Risks and Determination of Safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

No acute effects were identified in the toxicological studies for streptomycin; therefore, acute risk is not expected. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD: they are 91% of the cPAD for all infants less than 1 year old, the population subgroup with the highest exposure estimate. The short-term MOE is greater than the Agency's level of concern of 100: it is 260 for adults, the population group of concern. Intermediate-term or long-term residential exposures are not expected. Lastly, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA believes that there is a reasonable certainty that the potential dietary pesticide exposure will result in no harm to a user being treated therapeutically with streptomycin.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to streptomycin residues. More detailed information about the Agency's analysis can be found at <http://www.regulations.gov> in the document titled "Streptomycin. Section 3 Registration for Citrus Fruits Crop Group 10-10" in

IV. Other Considerations

A. Analytical Enforcement Methodology

A high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) is available for tolerance enforcement.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established any MRLs for streptomycin.

C. Revisions to Petitioned-For Tolerances

The tolerances proposed by the petitioner for the citrus fruit crop group 10-10 (0.50 ppm) and citrus dried pulp (3.5 ppm) are different from those which are being established by this document. This is primarily because the petitioner input the residue data differently into the calculation procedures for determining the proposed crop group tolerance (including all data for the representative crops into a single calculation). As a result, the tolerances are being established at 0.8 ppm for the fruit, citrus, crop group 10-10 and 3 ppm for fruit, citrus, group 10-10, dried pulp. In addition, the commodity definitions were corrected to reflect the crop group.

As a result of the IR-4 petition being withdrawn by the petitioner, EPA is not granting the request to establish the requested tolerances or to increase the tomato tolerance from 0.25 to 0.5 ppm. EPA is making the editorial changes requested by IR-4, however, including modifications

to the tolerance expression and tables contained in paragraph (a) and removal of expired grapefruit tolerances from paragraph (b).

V. Conclusion

Therefore, tolerances are established for residues of streptomycin in or on Fruit, citrus, group 10-10 at 0.8 ppm and Fruit, citrus, group 10-10, dried pulp at 3 ppm. In addition, existing tolerances in 40 CFR 180.245 are amended as follows: (1) consolidating the subparagraphs and tables in paragraph (a) into a single paragraph (a); (2) removing the time-limited tolerances for grapefruit and grapefruit, dried pulp, as they have expired; and (3) modifying the tolerance expression and creating a single paragraph and table under §180.245(a) to provide that in general tolerances are established for residues of the fungicide streptomycin, including its metabolites and degradates, in or on the commodities in the table to the paragraph. Compliance with the tolerance levels specified in the table is to be determined by measuring only streptomycin (O-2-Deoxy-2-(methylamino)-α-L-glucopyranosyl-(1-2)-O-5-deoxy-3-C-formyl-α-L-lyxofuranosyl-(1-4)-*N,N'*-bis(aminoiminomethyl)-D-streptamine) in or on the commodity.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork

Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule

in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 5, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.245 to read as follows:

§ 180.245 Streptomycin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide streptomycin, including its metabolites and degradates, in or on the commodities in Table 1 to this paragraph

(a). Compliance with the tolerance levels specified in Table 1 to this paragraph (a) is to be determined by measuring only streptomycin (O-2-Deoxy-2-(methylamino)-α-L-glucopyranosyl-(1-2)-O-5-deoxy-3-Cformyl-α-L-lyxofuranosyl-(1-4)-N,N'-bis(aminoiminomethyl)-D-streptamine) in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
Bean, dry, seed	0.5
Bean, succulent	0.5
Celery	0.25
Fruit, citrus, group 10-10	0.8
Fruit, citrus, group 10-10, dried pulp	3
Fruit, pome, group 11	0.25
Pepper	0.25
Potato	0.25
Tomato	0.25

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of streptomycin, in or on the agricultural commodities, as specified in Table 2 to this paragraph (b), resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels listed in Table 2 to this paragraph (b) is to be determined by measuring the levels of streptomycin only, in or on the commodities listed in this

Table 2 paragraph (b). The tolerances expire on the dates specified in Table 2 to this paragraph (b).

Table 2 to Paragraph (b)

Commodity	Parts per million	Expiration date
Fruit, citrus, group 10-10	2.0	12/31/22
Fruit, citrus, group 10-10, dried pulp	6.0	12/31/22

(c) – (d) [Reserved]

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